

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	West, Larry Eugene
Appl. No.	:	10/723,168
Filed	:	November 26, 2003
For	:	INTEGRATED BIO-REACTOR MONITOR AND CONTROL SYSTEM
Examiner	:	Bowers, Nathan Andrew
Group Art Unit	:	1797

DECLARATION UNDER 37 CFR §1.132
OF SCOTT T. BROADLEY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Scott T. Broadley, declare as follows:

1. I am a U.S. citizen residing at 6533 Hollywood Blvd., Los Angeles, CA 90028. I am the President of Broadley-James Corporation, which is the assignee of U.S. Patent Application Serial No. 10/723,168 (the “168 Application” entitled “INTEGRATED BIO-REACTOR MONITOR AND CONTROL SYSTEM,” which was filed on November 26, 2003. I have full knowledge of Broadley-James’ commercial success in using its unique methods and bio-reactor control system for monitoring and controlling cell growth processes in bioreactors; these same methods and systems are described and claimed in the ‘168 Application.

2. I have read the Office Action dated February 5, 2008 (hereinafter the “Office Action”) and understand that Claims 1-3, 5-11, 16-20, 23, 24, and 38 have been rejected under 35 U.S.C. §103(a) as obvious over various combinations of U.S. Pat. No. 6,385,496 (“Irwin”), U.S. Pat. Pub. No. 20050186671 (“Cannon”) and EP Application No. 0156176 (“Zeitlin”). The Office Action also indicates claims 21 and 22 were

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rejected under 35 U.S.C. § 103(a) as obvious over Irwin in view of Zeitlin as applied to claim 9, and further in view of U.S. Patent No. 6,048,721 ("Armstrong").

3. The Office Action states, in part, that

With respect to claims 1-3, 9-11, and 38 Irwin discloses a system for controlling a plurality of different reactor processes in a plurality of reactors (Figure 1:100, 200, 300). The reactors are coupled to a controller (Figure 1:12) over a selected communication network (Figure 1:18). The controller receives information from the reactors, and determines a control signal based on data representing conditions within each reactor. This is disclosed in column 4, line 32 to column 5, line 41... Irwin, however, does not expressly indicate that a utility tower is used to transmit detected conditions within the reactors to the controller.

Cannon discloses a bioreactor system in which a plurality of bioreactor assembly cartridges (Figures 1-3) are positioned within a incubator rack (Figure 4). Each bioreactor assembly includes a media reservoir (Figure 6:22), a bioreactor (Figure 6:10) and at least one flow sensor (Figure 6:13). This is disclosed in paragraph [0052]. Cannon teaches in paragraph [0083] that data obtained by each of the sensors in each of the bioreactor assemblies is first sent to a utility tower in the form of an amplifier or a transmitter, and then it is sent a controller via a communication path or bus. At the time of the invention, it would have been obvious to one of ordinary skill in the art to provide the system for controlling a plurality of different reactors disclosed by Irwin with a common utility tower means configured to sense conditions in the plurality of reactors. Office Action, Section 1.

The Office Action further states,

The Irwin reference still differs from Applicant's claim invention because Irwin does not expressly disclose that the reactors are bioreactors.

As discussed above, Cannon discloses a bioreactor system in which culturing parameters such as temperature, dissolved gas concentration and glucose concentration are monitored.

Zeitlin discloses a system for controlling a plurality of reactors (Figure 1:15) using controllers (Figure 1:10, 11, 12, 13, 20). Zeitlin indicates on page 7, lines 21-28 and page 9, lines 1-27 that air flow, oxygen flow, agitator speed, foam, pH and temperature levels within the bioreactor are monitored and regulated using the controllers...

At the time of the invention, it would have been obvious to one of ordinary skill in the art that the control system disclosed by Irwin would be fully capable of regulating the operation of a plurality of bioreactors. It would have been apparent to use the system of Irwin to monitor and control certain parameters, such as agitation, temperature and fluid flow, that are critical to fermentation processes. Office Action, Section 1.

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I do not agree with the Examiner's remarks that it would have been obvious to one of skill in the art to combine the cited references to make the claimed invention. Broadley-James' automated bioreactor control system "BioNet®" incorporates one or more of the claimed features of the invention. Even if the cited art, when combined, could be interpreted as showing all of the features in the pending claims (and I do not agree that it does), the fact that Broadley-James' BioNet® product has, virtually overnight, become a commercial success, illustrates that it would not be obvious to one of ordinary skill in the art to piece together portions of the systems disclosed in the cited references to make the claimed invention.

4. BJC began its corporate investigation of automated bioreactor controls at least as early as November 2001. At that time there were some bioreactor control systems which often required manual intervention. However, there were no bench-top automated bioreactor control systems that included the features as claimed in the '168 application. Throughout 2002 and 2003, Broadley-James continued investigating potential bioreactor controller configurations, and developed and refined its BioNet® bioreactor controller. Broadley-James invested many man-years and hundreds of thousands of dollars to first investigate the possibility of building an automated bioreactor control system and then develop BioNet®. As part of its extensive development effort, Broadley-James devised a bioreactor controller that includes a uniquely configured utility tower and controller, and a communication network connecting the utility tower and the controller.

5. Broadley-James BioNet® controller includes features described in the '168 application, for example, a first and second communication network, and the controller and utility tower as recited in pending claims 1, 3, and 38. At the time of the invention, these features were unique to BioNet®.

6. Broadley-James did not manufacture or sell any automated bioreactor control systems prior to developing BioNet®. Instead, Broadley-James sold instrumentation such as pH probes and other equipment for use in fermentation or cell growth chambers. Cell-growth technology is extremely complex, and bioreactor control systems are applicable only to a niche market with a limited number of potential

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customers. However, despite entering into a brand new area of business that has a relatively small potential market, Broadley-James achieved immediate commercial success with BioNet®, largely due to its unique features and configuration. These same features are claimed in the '168 application. BioNet® sales have increased dramatically over the past few years, as shown in the following Broadley-James' invoice amounts for BioNet® projects during the past five calendar years:

2003: \$ 544,322.30
2004: \$1,240,464.40
2005: \$3,173,004.81
2006: \$3,116,941.84
2007: \$6,556,535.00

7. To date, Broadley-James has invoiced more than \$14,631,266 for its BioNet® product. To provide context to this data, between about September 2006 and September 2007, I believe Broadley-James's BioNet® product accounted for 30-50% of the market share for these types of control systems. Capturing a large market share in just five years indicates that customers recognize the commercial benefits of the unique features found in BioNet®, the same features as claimed in the '168 application. After observing the commercial success of Broadley-James' BioNet®, competitors have now begun to emerge with their own bioreactor control products. These other companies often compare their products to BioNet® and/or discuss Broadley-James BioNet® system in their marketing material.

8. Because of its limited and highly specialized market, a bioreactor controller is not the type of product that can be easily sold through wide-spread advertising. Instead, Broadley-James relies on trade show demonstrations, selective industry advertising, and specifically directed customer interaction to sell BioNet®. Accordingly, the commercial success of BioNet® is not due to an extensive marketing campaign. Instead, its commercial success is a result of its innovative and unique configuration which offers customers a flexible, cost-effective and scalable solution to bioreactor control.

9. I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

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10. The undersigned declares further that all the statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 31-MAR-2008

Signed: Scott T. Broadley
Scott T. Broadley

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